

AMENDMENT AND RESPONSE TO OFFICE ACTION

Amendment

In the claims

1. (currently amended) A drug formulation comprising
a drug selected from the group consisting danazol, bromocriptine, and luteinizing
hormone-releasing hormone (LHRH) analogues in an amount effective to provide regional, not
systemic, relief from benign diseases or disorders of the breast

in a pharmaceutically acceptable carrier selected from the group consisting of a
hydroalcoholic gel, ointment, lotion, emulsion, cream, foam, mousse, liquid, spray, and aerosol
pharmaceutical carrier capable of delivering the drug to the breast tissue, comprising a
transdermal penetration enhancer to promote delivery of the drug across the stratum corneum, in
a dosage which results in low serum drug levels as compared to the systemic administration of
the drug.

2. (original) The drug formulation of claim 1 wherein the drug is soluble in aqueous
solutions.

3. (original) The drug formulation of claim 1 wherein the drug is in the form of micro- or
nano-particulates.

4. (previously presented) The drug formulation of claim 1 wherein the carrier is selected
from the group consisting of a gel, ointment, lotion, emulsion, cream, foam, mousse, liquid,
spray, and aerosol.

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5. (currently amended) The drug formulation of claim 1 3, wherein the carrier is a hydroalcoholic gel and the alcohol is a penetration enhancer.

6. (cancelled)

7. (previously presented) The drug formulation of claim 1 wherein the drug is selected from the group consisting of danazol and bromocriptine.

8. (previously presented) The drug formulation of claim 3 wherein the drug is a danazol.

9. (cancelled)

10. (withdrawn, currently amended) A method for treating a disease or disorder of the breast comprising

topically administering to the breast of a patient,

a drug formulation suitable for local or regional delivery comprising an effective amount of drug selected from the group consisting of danazol, bromocriptine, and luteinizing hormone-releasing hormone (LHRH) analogues ~~to provide regional, not systemic, relief from benign diseases and disorders of the breast,~~

~~in a pharmaceutically acceptable carrier selected from the group consisting of a hydroalcoholic gel, ointment, lotion, emulsion, cream, foam, mousse, liquid, spray, and aerosol pharmaceutical carrier capable of delivering the drug to the breast tissue, comprising a transdermal penetration enhancer to promote delivery of the drug across the stratum corneum, in a dosage which results in low serum drug levels as compared to the systemic administration of the drug.~~

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11. (withdrawn) The method of claim 10 wherein the drug is in the form of micro- or nano-particulates.

12. (withdrawn, previously presented) The drug formulation of claim 10 wherein the carrier is selected from the group consisting of a gel, ointment, lotion, emulsion, cream, foam, mousse, liquid, spray, and aerosol

13. (cancelled)

14. (withdrawn, currently amended) The method of claim 11 ~~13~~ wherein the drug is selected from the group consisting of danazol and bromocriptine.

15. (withdrawn, previously presented) The method of claim 11 wherein the drug is danazol.

16. (cancelled)

17. (withdrawn, previously presented) The method of claim 10 wherein the benign disease of the breast is selected from the group consisting of mastalgia, mastodynia, Mondor's disease, fibrocystic breast disease, costochondritis, mastitis, Paget's disease of the areola, fibroadenoma, breast abscess, and breast infections.

18. (cancelled)

19. (withdrawn, previously presented) The method of claim 10 wherein the region is the breast, areola, and underlying musculature of the chest.